

§ 607.35 Notification of registrant; blood product establishment registration number and NDC Labeler Code.

(a) The Director of the Center for Biologics Evaluation and Research will provide to the registrant a validated copy of Form FD-2830 (Blood Establishment Registration and Product Listing) as evidence of registration. This validated copy will be sent to the location shown for the registering establishment, and a copy will be sent to the reporting official if at another address. A permanent registration number will be assigned to each blood product establishment registered in accordance with these regulations.

(b) If a registered blood product establishment has not previously participated in the National Drug Code system, or in the National Health Related Items Code system, the National Drug Code (NDC) numbering system shall be used in assigning the first five numeric characters, otherwise known as the Labeler Code, of the 10-character NDC Code. The Labeler Code identifies the manufacturer.

(c) Although establishment registration and blood product listing are required as described in § 607.20, validation of registration and the assignment of a NDC Labeler Code do not, in themselves, establish that the holder of the registration is legally qualified to deal in such products.

[40 FR 52788, Nov. 12, 1975, as amended at 49 FR 23833, June 8, 1984; 66 FR 59159, Nov. 27, 2001]

§ 607.37 Inspection of establishment registrations and blood product listings.

(a) A copy of the Form FD-2830 (Blood Establishment Registration and Product Listing) filed by the registrant will be available for inspection under section 510(f) of the act, at the Department of Health and Human Services, Food and Drug Administration, Office of Communication, Training and Manufacturers' Assistance (HFM-40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, suite 200N, Rock-

ville, MD 20852-1448. In addition, for domestic firms, the same information will be available for inspection at each of the Food and Drug Administration district offices for firms within the geographical area of such district office. Upon request and receipt of a self-addressed stamped envelope, verification of registration number, or location of registered establishment will be provided. The following information submitted under the blood product listing requirements is illustrative of the type of information that will be available for public disclosure when it is compiled:

- (1) A list of all blood products.
- (2) A list of all blood products manufactured by each establishment.
- (3) A list of blood products discontinued.
- (4) All data or information that has already become a matter of public knowledge.

(b) Requests for information regarding blood establishment registrations and blood product listings should be directed to the Department of Health and Human Services, Food and Drug Administration, Office of Communication, Training and Manufacturers' Assistance (HFM-40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448.

[40 FR 52788, Nov. 12, 1975, as amended at 49 FR 23833, June 8, 1984; 55 FR 11014, Mar. 26, 1990; 66 FR 59159, Nov. 27, 2001]

§ 607.39 Misbranding by reference to establishment registration or to registration number.

Registration of an establishment or assignment of a registration number or assignment of a NDC number does not in any way denote approval of the firm or its products. Any representation that creates an impression of official approval because of establishment registration or possession of registration number or NDC number is misleading and constitutes misbranding.